REMARKS

Claims 7, 8 and 11 are pending in the present Application. No claims have been amended and no claims have been added, leaving claims 7, 8 and 11 for consideration upon entry of the present Response.

Priority

In this Office Action, the Examiner noted that certified copies of foreign applications have not been filed a required by 35 U.S.C.119(b). (Office Action dated 3/20/2009, page 3) In the previous response, we noted to the Examiner that this application was a 371 national stage entry of a PCT claiming priority to Korean Patent Application No. 10-2004-0011327 and Korean Patent Application No. 10-2005-0013395 and that copies of these documents should have been provided to the USPTO by the International Bureau. (Amendment and Response filed 12/10/2008) A copy of the of PCT/IB/304 was filed on 12/10/2008. However, as noted by the Examiner, the copy of PCT/IB/304 filed on 12/10/2008 indicated that the a copy of the Korean Patent Application No. 10-2004-0011327 had not been received ("NR").

Attached herewith is an updated copy of PCT/IB/304 to document that certified copies of the two priority applications were indeed received by the International Bureau. The attached copy of PCT/IB/304 recites:

Priority Date	Priority Application No	Country or regional Office or PCT receiving Office	Date of receipt of priority document
20 February 2004 (20.02.2004)	10-2004-0011327	KR	19 April 2005 (19.04.2005)
18 February 2005 (18.02.2005)	10-2004-0013395	KR	19 April 2005 (19.04.2005)

Thus, the attached copy of PCT/IB/304 clearly states that both Korean Patent Application No. 10-2004-0011327 and Korean Patent Application No. 10-2005-0013395 were received by the IB on 19 April 2005 (19.04.2005). Therefore, Applicants believe that the USPTO should have received a certified copy of Korean Patent Application No. 10-2004-0011327 and Korean Patent Application No. 10-2005-0013395 via the International Bureau, thus meeting the requirements 35 U.S.C.119(b).

In this Office Action, the Examiner noted that a translation of the foreign document has

not been received. (Office Action dated 3/9/2009, page 3) Applicants respectfully submit that an English language translation of a non-English language foreign application is not required except: (A) when the application is involved in interference, (B) when necessary to overcome the date of a reference relied upon by the examiner, or (C) when specifically required by the examiner. (37 CFR § 1.55(a)(4)) Thus, Applicants believe that an English Translation (certified copy) is not required at this time.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 7-8 and 11 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement because the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to a person skilled in the pertaining art to make and/or use the invention. (Office Action dated 3/9/2009, page 3) Applicants respectfully traverse this rejection.

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 219 (CCPA 1976).

Applicants contend that claims 7-8 and 11 meet the enablement requirement. The specification discloses the nucleotide sequence of SEQ ID NO 5 (see sequence listing), and teaches, as evidenced by an association study, that the alleles of the SNP at position 101 of the sequence are associated with an increased risk of developing colorectal cancer in a Korean human having the appropriate base at the SNP site (see Table 1). Applicants note that for the SNP at position 101 of SEQ ID NO 5 the chi-square p-value of 4.62×10^{-3} is related to comparing genotype frequency in the case vs. control groups (page 7, lines 1-10). Applicants respectfully submit that when the p-value ≤ 0.05 it is considered that the genotype of the case group is different from that of the normal group. (page 7, lines 1-10) The chi-value and chi-exact-p-value previously calculated were described in Table 1. The chi-value and chi-exact-p-value demonstrate different genotype frequencies in a specific SNP between a patient and a normal person. In Table 1, where the p-value is ≤ 0.05, there is a significant difference between a patient group and a normal person group. Thus, a chi-square p-value of 4.62×10^{-3} clearly indicates that there are

significant differences between expected values and measured values in genotype frequency at the polymorphic site at position 101 of SEQ ID NO: 5.

In making the rejection, the Examiner asserted "The data provided in Table 1 is not clear whether the statistics is related to the allele frequency data or the genotype frequency." (Office Action date 3/9/2009, page 5) Applicants respectfully disagree. With regard to the chi-square p-value, Applicants direct the Examiners attention to page 7, lines 1-10, which indicates that the chi-square p-value is related to the genotype frequency. Thus, Table 1, in view of page 7, lines 1-10, clearly demonstrate that the chi-square p-value is calculated based on the genotype frequency.

Further, the specification demonstrates that the odds ratio of 1.52 represents the ratio of the probability of risk allele in the case group to the probability of the risk allele in the normal group (page 7, lines 15-17). Applicants respectfully submit that if a value of OR (odds ratio) is equal 1, this means that a ratio of an incidence rate of disease in the patient to an incidence rate of the disease in the normal person is 1:1. If a value of OR is greater than 1, this means that an incidence rate of disease in one having a specific risk allele is more than an incidence rate of disease in one not having the specific risk allele. In Table 1, in the case of the CCY-041 marker, when the base is G, a value of OR is 1.52, thereby indicating that the incidence rate of disease is 1.52 times higher, compared with when the base is T. More directly, Applicants respectfully assert that that an odds ratio falling within the range of 1.30 to 2.06 shows that the polymorphic marker is associated with colorectal cancer (page 8, lines 1-7).

Thus, Table 1 shows an incidence rate of disease of a model having a specific risk allele or not having a specific risk allele. Therefore, an incidence rate of disease of one having the GT hetero genotype is 1.52 times higher than an incidence rate of disease of one having the TT homo genotype. Therefore, Applicants respectfully assert that the present invention may be used to diagnose a cancer in one having the hetero genotype.

In addition, as noted above, the Examiner asserts "The data provided in Table 1 is not clear whether the statistics is related to the allele frequency data or the genotype frequency." (Office Action date 3/9/2009, page 5) Applicants respectfully disagree. With regard to the odds ratio, Applicants direct the Examiners attention to page 7, lines 15-20, which clearly indicates that the odds ratio is related to the risk allele frequency. Thus, Table 1, in view of page 7, lines 15-20, clearly demonstrate that the odds ratio is calculated based on the risk allele frequency.

The specification further demonstrates that the confidence interval of 1.182 and 1.961 for

the SNP at position 101 of SEQ ID NO 5 are related to the association of the risk allele with disease. (page 7, lines 17-20) Applicants respectfully assert that Table 1, in view of page 7, lines 17-20, demonstrate that the confidence interval is calculated based on the risk allele frequency.

In making the rejection, the Examiner further stated "it is unclear whether the statistics, analyzed the genotype, i.e., GG, GT or TT status or whether the statistics analyze the allele status, i.e., G or T." (Office Action dated 3/9/2009, page 7). As noted above, Table 1, in view of page 7, lines 1-10, demonstrate that the chi-square p-value is calculated based on the genotype frequency (i.e., the chi-square p-value statistics analyzed the genotype, i.e., GG, GT or TT status); Table 1, in view of page 7, lines 15-20, demonstrate that the odds ratio is calculated based on the risk allele frequency (i.e., the odd ratio statistics analyzed the analyze the allele status, i.e., G or T); and Table 1, in view of page 7, lines 17-20, demonstrate that the confidence interval is calculated based on the risk allele frequency (i.e., the confidence interval statistics analyzed the analyze the allele status, i.e., G or T). For these reasons at least, Applicants believe that Table 1, in view of the specification at page 7, lines 1-20 is clear regarding whether the statistics, analyzed the genotype, i.e., GG, GT or TT status or whether the statistics analyze the allele status, i.e., G or T. In view of the data provided in the specification, Applicants submit that Table 1 clearly demonstrates that by determining the base at the polymorphic site is a G compared with determining the base is a T indicates the Korean human is at an increased risk of developing colorectal cancer, regardless of whether the Korean human has a GT or GG genotype.

In summary, Applicants believe that Table 1 demonstrates that the SNP at position 101 of SEQ ID NO 5 is associated with colorectal cancer and that by determining the base at position 101 of SEQ ID NO 5 is guanine (G) indicates an increased risk of developing colorectal cancer compared to determining the base is thymine (T). For this reason at least, Applicants believe that the specification fully enables one of skill in the art to make and use the claimed invention without undue experimentation. Applicants request a withdrawal of the rejection and allowance of the claims.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

CANTOR COLBURN LLP

By__/Ian J.S. Lodovice/_____
Ian J.S. Lodovice
Registration No. 59,749

Date: July 7, 2009
CANTOR COLBURN LLP
20 Church Street, 22nd Floor
Hartford, CT 06103
Telephone (860) 286-2929
Facsimile (860) 286-0115
Customer No.: 23413